



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. FDA-2009-N-0114]

RIN 0910-AF88

Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect recent statutory amendments to the device registration and listing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Food and Drug Administration Amendments Act of 2007 (FDAAA), enacted on September 27, 2007, amended the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In addition, this final rule would facilitate FDA's collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The final rule will update certain provisions in the regulations to improve the quality of registration and listing information available to FDA. FDA

relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

DATES: This final rule is effective October 1, 2012.

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I. Background

We originally published establishment registration regulations for medical devices in the Federal Register of September 3, 1976 (41 FR 37458) (proposed rule) and August 23, 1977 (42 FR 42520) (final rule), and device listing regulations in the Federal Register of September 30, 1977 (42 FR 52808) (proposed rule), and August 25, 1978 (43 FR 37990) (final rule).

These regulations called for establishment registration and device listing information to be submitted to the Center for Devices and Radiological Health (CDRH) on several paper forms: FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing. Once these forms were completed and submitted to FDA, FDA then forwarded them to a data entry contractor who entered the information into FDA's device registration and listing database.

In June 2002, section 321 of the Bioterrorism Act (Public Law 107-188) amended section 510(i) of the FD&C Act (21 U.S.C. 360(i)) to require those foreign establishments who are required to register with FDA to do so by electronic means, and to include additional information identifying certain parties involved in the importation of the foreign establishment's devices into the United States as part of their registration. Subsequently, in October 2002, section 207 of the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107-250) further

amended section 510 of the FD&C Act by extending the requirement for electronic submission of registration information to include domestic firms as well as foreign firms. However, when adding these new electronic submission requirements, which appear in section 510(p) of the FD&C Act, Congress chose to delay their implementation so that FDA would have an opportunity to first put systems in place to accommodate the electronic receipt of registration information. This was accomplished by including a requirement in section 510(p) of the FD&C Act for the Secretary of the Department of Health and Human Services (the Secretary) to make a finding that the electronic receipt of registration information was feasible before implementing electronic registration.

As reflected in FDAAA (Public Law 110-85), the most recent legislation establishing changes to FDA's device registration and listing program, FDA has now developed a system that makes the electronic receipt of device registration and listing information feasible. FDAAA amended section 510(p) of the FD&C Act by eliminating the need for a feasibility finding, and requiring both foreign and domestic establishment registration and device listing information to be submitted using electronic means unless FDA grants a waiver request. In accordance with FDAAA, FDA's Unified Registration and Listing System (FURLS) for devices, which is a new Internet-based system, became operational on October 1, 2007. FDA believes this electronic system will ultimately make the process of submitting registration and listing information for devices more efficient for industry and will provide faster access to this information for both FDA and industry.

In addition, the new electronic system will allow FDA to more effectively gather information concerning marketed devices. We rely on having complete and accurate registration

and listing information to accomplish a number of important statutory and regulatory objectives.

For example, we use registration and listing information to:

- Identify establishments producing marketed medical devices;
- Identify establishments producing a specific device when that device is in short supply or is needed for a national emergency. This information helps us facilitate prompt shipment of devices to the places where they are needed most. For example, during a bioterrorism incident, we could use device listing information to identify establishments that could be helpful in preventing or counteracting the deadly effects of biological weapons; with this information, we could facilitate prompt shipment of the devices as needed;
- Facilitate the recall of devices marketed by owners or operators of device establishments;
- Identify and catalogue marketed devices;
- Administer our postmarketing surveillance programs for devices;
- Identify devices marketed in violation of the law;
- Identify and control devices imported or offered for import into the country from foreign establishments; and
- Schedule and plan inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

We also rely on registration and listing information to help us comply with several other statutory provisions. For example, we use this information to generate accurate estimates of the number of businesses that are affected by our rulemaking activities. These estimates help us assess the impact of our regulations on regulated industry, which we are required to do under the

Regulatory Flexibility Act of 1980 (Public Law 96-354) (5 U.S.C. 601-612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Public Law 104-121); the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) (2 U.S.C. 1501 et seq.); the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520); Executive Order 12866 (September 30, 1993); and the Congressional Review Act (section 251 of Public Law 104-121).

Registration and listing information will continue to be used for all of the important public health purposes outlined in this document. The electronic submission of registration and listing information allows us to use such information more quickly and effectively to carry out all of the activities described in this document.

In addition, electronic submission of registration and listing information furthers the purpose of the Government Paperwork Elimination Act of 1998 (Public Law 105-277, Title XVII) (GPEA). GPEA requires Federal Agencies to give persons who are required to maintain, submit, or disclose information, the option of doing so electronically when practicable as a substitute for paper, and to use electronic authentication (electronic signature) methods to verify the identity of the sender and the integrity of the electronic content. We believe that electronic submission of registration and listing information furthers the purpose of this law and makes the registration and listing processes more efficient and effective both for industry and us.

To implement the FDAAA and Bioterrorism Act amendments to section 510 of the FD&C Act, FDA published in the Federal Register of March 26, 2010 (75 FR 14510), a proposed rule to amend its regulations governing medical device establishment registration and device listing (the March 2010 proposed rule). The comment period closed on June 24, 2010.

II. Overview of the Final Rule

A. Significant Changes to the Proposed Rule

FDA made no significant changes to the proposed rule.

B. Highlights of the Final Rule

1. Switch to an Electronic Registration and Listing System

This final rule updates the regulations to conform to the requirement in section 510(p) of the FD&C Act, as amended by FDAAA, that registration and listing information be provided to FDA electronically unless FDA grants a request for a waiver.

As part of the new electronic registration and listing system, each owner or operator establishes an account on FDA's online device establishment registration and device listing system, FURLS, which the owner or operator uses to create and update his or her device establishment registration and device listing information. Information submitted to FDA prior to September 15, 2007, has already been migrated to the new FURLS electronic database and thus there is no need for owners or operators to reenter this information.

In accordance with section 510 of the FD&C Act, as amended by sections 222 through 224 of FDAAA, device establishment owners and operators have been using FURLS to submit their establishment registration and device listing information electronically since the system became operational on October 1, 2007. In addition, in accordance with section 510(p) of the FD&C Act, as amended by FDAAA section 224, FDA is granting waivers from the new electronic submission requirements only to those owners or operators for whom electronic registration and listing is not reasonable.

2. Foreign Establishment Registration and Listing Requirements of the Bioterrorism Act

Before its devices will be allowed into the United States, each foreign establishment that is required to register must supply to FDA the registration information required by part 807, including the name and contact information for its U.S. agent. Section 321 of the Bioterrorism Act affected foreign establishment registration in part by amending section 510(i) of the FD&C Act to require, as part of an establishment's registration, the name of each importer of the device that is known to the establishment and the name of each person who imports or offers to import the device into the United States. This final rule amends part 807 to reflect in our regulations the Bioterrorism Act requirement that foreign establishments whose devices are imported or offered for import into the United States must identify: (1) All importers known to the foreign establishment and (2) the name of each person who imports or offers to import the foreign establishment's device into the United States. The final rule revises § 807.3 to add specific definitions for these two new categories of information that need to be submitted by foreign establishments.

The final rule eliminates the exemption in § 807.40(a) for foreign establishments whose devices enter a foreign trade zone and are re-exported from the foreign trade zone without entering U.S. commerce, and also eliminates the exemption in § 807.40(c) for devices that are imported under section 801(d)(3) of the FD&C Act (21 U.S.C. 381(d)(3)). Removing the exemptions from registration and listing requirements for devices entering foreign trade zones and for products imported under section 801(d)(3) of the FD&C Act is consistent with Congress' desire, as reflected in the Bioterrorism Act, to increase the Nation's ability to prepare for and effectively respond to bioterrorism and other public health emergencies by requiring foreign establishments to provide more, rather than less, information for imported products. For

example, registration and listing information for devices imported into foreign trade zones and devices imported under section 801(d)(3) of the FD&C Act will help us identify and contact foreign establishments that export to the U.S. devices for which there may be a domestic shortage in an emergency.

3. Change in Requirements Relating to Contract Manufacturers and Sterilizers

The final regulation also amends part 807 to modify § 807.20(a)(2) and removes § 807.20(c)(1) and (c)(2) such that all contract manufacturers and contract sterilizers are required to register their establishments and list their devices. FDA relies on having a complete and accurate registration of device establishments and listing information for devices processed at those establishments in order to accomplish a number of important statutory and regulatory objectives. For example, when an establishment experiences a problem, it can have a significant impact on the product lines for one or multiple firms for which it is contracted to provide manufacturing or sterilization services. Knowing which products are manufactured or sterilized at the affected site could facilitate the recall of the impacted devices. FDA also believes that knowing that these manufacturing sites exist would be critical information when a device is in short supply or needed in the event of a national emergency.

4. Requiring Submission of the FDA Product Code Assigned to a Device Rather Than the Classification Name and Number

The new electronic system requires exempt devices to be identified by product code rather than by classification name and number. The product code is already requested for such devices. This change to the regulation codifies the existing practice.

5. Requiring Submission of the 510(k) or the Humanitarian Device Exemption (HDE) Number for Non-Exempt Device Listings

Section 807.25(g)(4) of the final regulation also codifies the practice of including the 510(k) number when listing a medical device that has gone through premarket clearance or the approved HDE number in the electronic device registration and listing system. This change also provides FDA with a tool to help ensure that devices that lack a required premarket clearance or premarket approval are not marketed.

6. Identification of a Contact Person to Administer the Electronic System Accounts

As a result of the passage of FDAAA, FDA began collecting device registration and listing information using FURLS beginning in October 2007. When using FURLS, an owner or operator needs to identify not only an official correspondent for the establishment but also a contact person for the owner or operator. The contact person is the only person who can administer the owner or operator's user accounts in FURLS.

In instances where owners or operators have only one establishment, they may choose the same person to serve as both the contact person for the user account and the official correspondent for the establishment. For owners or operators with multiple establishments, the contact person for the owner or operator may also serve as the official correspondent for any or all of the owner or operator's establishments. Alternatively, using the accounts management software for FURLS, the owner or operator may create subaccounts in which different official correspondents are identified for each establishment.

Proper control of access to accounts and control of the ability to update an establishment's online information is necessary to avoid errors. Therefore, the final rule requires that each owner or operator identify only one contact person within the owner or operator's

organization who will be responsible for creating the master account in FURLS for the owner or operator and assigning subaccounts to each establishment, if needed. Once the contact person creates the master account and any needed subaccounts, the official correspondent can then use the accounts to submit the owner or operator's establishment registration and device listing information to FDA.

7. Establishment Operations Will Be Reported Through Device Listing

The final rule requires owners or operators to identify the operations or activities their establishments engage in only as part of their device listings. This is because the new electronic system has been designed to automatically migrate the information provided in the device listing to the owner or operator's registration, thus saving the owner or operator from having to provide the same information twice. Because under the new system owners or operators would only have to supply such information once, this change will save time and help avoid inconsistencies between the registration and listing information for a single establishment.

8. Registration Fees

FDAAA section 212 requires that certain medical device establishments pay a registration user fee when they initially register with FDA and for each annual registration thereafter. The final rule, therefore, removes the sentence at the beginning of § 807.20(b) that states "[n]o registration or listing fee is required."

9. Definition of Restricted Devices

The final rule revises the definition of "restricted device" in § 807.3(i) to more accurately reflect the provisions of the FD&C Act that provide us with authority to restrict devices.

III. Comments on the Proposed Rule

In the March 2010 proposed rule, FDA proposed to amend its regulations governing medical device establishment registration and device listing. FDA provided 90 days for the submission of comments from interested parties. FDA received three sets of comments which FDA summarizes and discusses in this section of this document.

(Comment 1) Two comments objected that it is not necessary for contract manufacturers and contract sterilizers to list all products, since these contractors are typically not responsible for putting the contracted products into the marketplace. The comments stated that such a requirement would: (1) Duplicate information already submitted by the manufacturer; (2) increase the risk that inaccurate information was submitted to FDA because contract manufacturers are not in the best position to inform FDA when commercial distribution of a device has commenced, ceased, or resumed; and (3) reveal confidential business partnerships to competitors.

(Response) FDA disagrees with these comments. FDA does not consider the requirement that contract sterilizers and manufacturers list devices to be duplicative. While registration provides valuable information regarding, for example, the location of device establishments, this value is limited if we do not also know what devices are being manufactured and sterilized at the establishments. FDA relies on having a complete and accurate registry of device establishments and a list of devices processed at those establishments in order to accomplish a number of important statutory and regulatory objectives. For example, having basic information about where devices are made and cleaned will enable us to respond in a more timely and effective fashion in the case of an adverse event or defect associated with a particular device or if there is a shortage of a particular device in the event of a national emergency.

FDA does not believe that the final rule will increase the risk that inaccurate listing information is submitted to FDA. Contract manufacturers and contract sterilizers, as with other establishments, will be required to register and list within 30 days of entering into such operation and review and update listing information annually. Contracting entities will be responsible for providing accurate information to FDA and should know what devices they manufacture or sterilize at their establishment.

Finally, requiring contract manufacturers and sterilizers to submit listing information to FDA will not reveal confidential business partnerships to competitors. Under 21 CFR 20.116, public disclosure of establishment registration and device listing information is governed entirely by § 807.37, which addresses how such information will be subject to inspection in accordance with section 510(f) of the FD&C Act. FDA has revised § 807.37 to reflect its plans to exclude from public inspection or posting on the FDA Web site brand names and premarket submission numbers of devices manufactured or sterilized by a contractor that would reveal confidential business relationships, and plans to add a mechanism in FURLS to allow entities to indicate whether they believe information should not be made public under this standard. We also revised § 807.37 to make clear that FDA-assigned listing numbers will also not be publicly available or posted on the public FURLS Web site. Listing numbers serve important governmental functions that may be harmed if they were made public.

(Comment 2) One comment questioned requiring contract manufacturers to register because contract manufacturers have a one-to-one relationship with finished device manufacturers that would not be of benefit in providing enhanced manufacturing when devices are in short supply.

(Response) FDA disagrees. By statute, all establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a device (including repackaging and relabeling) are required to register unless specifically exempted by regulation. See sections 510(a) to (d), (i) and (g) of the FD&C Act. Contract manufacturers are engaged in these activities, and FDA believes that the registration of their establishments is not unnecessary to the protection of the public health. For example, this information would provide us with basic information about the entities that make devices, facilitating a timely and effective response to adverse events, shortage, or other device problems associated with one of these establishments, in addition to potentially assisting with device shortages. The information would also assist us in our fundamental regulatory activities, such as planning and scheduling inspections.

(Comment 3) One comment suggested that FDA add a new registration type for foreign establishments that import devices into foreign trade zones.

(Response) FDA believes that foreign establishments that import devices into foreign trade zones should be treated the same as other establishments that must register and list. FDA agrees, however, that it is important to capture whether an establishment is importing devices into foreign trade zones and will add an establishment type to the existing list of establishment types in FURLS to cover this activity.

(Comment 4) One comment disagreed with FDA's proposed revocation of the exemption in § 807.40(a) for devices from foreign establishments that enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U.S. commerce. The comment questioned whether the Bioterrorism Act would require the revocation of the exemption and whether the U.S. Customs and Border Protection Customs-Trade Partnership Against Terrorism

and the Customs Advance Manifest Rule would provide FDA access to verification that devices for export are re-exported and information about the shipper, cargo, and consignee.

(Response) FDA disagrees. The removal of the exemption increases the United States' ability to defend against and respond to bioterrorism by providing FDA with additional information regarding foreign establishments and devices manufactured at those establishments that are shipped into the United States, which is consistent with the goals of the Bioterrorism Act. For example, this information could be used to address a device shortage in an emergency.

(Comment 5) One comment urged FDA to revise § 807.40 to include a list of activities that require foreign establishment registration that parallels the list in § 807.20(a) of activities that require registration of domestic establishments.

(Response) FDA declines to revise the rule as suggested by the comment, as the list of activities in § 807.20(a), which is not all-inclusive, already applies to both domestic and foreign establishments. FDA does want to emphasize, however, that it considers a foreign establishment that only exports devices to the United States to be engaged in the manufacture, preparation, propagation, compounding, or processing of a device, and it therefore must register and list. Further, § 807.40(c) prohibits a device from being imported or offered for import into the United States unless it is the subject of a device listing and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. Thus, a device may not enter the country unless valid registration and listing information are provided. This information is used, for example, by verifying that medical devices entering the United States are exported from legitimate sources, are not counterfeit, and are legally marketed in the United States.

(Comment 6) One comment urged that § 807.25(a) discuss the part 11 (21 CFR part 11), Electronic Records, Electronic Signatures responsibilities of a party using the FDA-supplied FURLS system.

(Response) FDA declines to revise the rule as suggested by the comment. Under § 807.25(a), the submission of registration and listing information must be made in accordance with part 11, with certain exceptions. See discussion in the preamble to the March 2010 proposed rule (75 FR 14510 at 14523) and FDA's guidance on part 11 referenced therein.

(Comment 7) Citing the preamble to the March 2010 proposed rule (75 FR 14510 at 14516), one comment expressed concerns about combination products having to register and list with, and pay fees to, more than one Center. The comment urged FDA to add a flag to a listing that identifies a combination product.

(Response) As reflected in the preamble to the March 2010 proposed rule, the Agency is currently working to develop and implement a more streamlined approach to facility registration and product listing for combination products. User fees are outside the scope of this rule. We intend to address these issues in the future. For efficient, effective regulation of combination products, FDA intends to add a flag to identify whether a listing is for a combination product.

(Comment 8) One comment urged FDA to revise § 807.25(g)(4) to list the submission types.

(Response) FDA declines to revise the rule as suggested by the comment. However, we revised §§ 807.25(g)(4) and 807.3(w) to make clear that they include the premarket submission number for granted de novo petitions for classification under section 513(f) of the FD&C Act (21 U.S.C. 360c(f)), which are currently given a number preceded by the letter "K".

(Comment 9) One comment urged that owner-operators be given the ability to assign individuals to have "View Only" access to FURLS.

(Response) This comment asks for a change beyond the scope of this rulemaking.

(Comment 10) One comment urged that private label manufacturers should not have to submit brand names considered trade confidential under § 807.25(b). Alternatively, the comment urged FDA to restrict access to information considered to be trade confidential to FDA and the FURLS account owner.

(Response) FDA declines to remove this requirement from the rule. Requiring private label manufacturers to submit brand names to FDA will not reveal this information to the public. FDA has revised § 807.37 to reflect its plans to exclude from public inspection or posting on the FDA Web site brand names and premarket submission numbers of devices marketed by a private label manufacturer that would reveal confidential business relationships, and plans to include a mechanism in FURLS to allow entities to indicate whether they believe information should not be made public under this standard.

(Comment 11) One comment urged FDA to describe the timeline that applies to establishment registration and provide acknowledgment of successful registration.

(Response) FDA agrees that describing the timeline that applies to establishment registration is important, which is why § 807.22, "Times for establishment registration and device listing," provides timelines for registration. To be clear that § 807.28 governs conditions that require that listing information be updated, and not the time at which listing must be updated, which is governed by § 807.22, we changed four occurrences of "when" to "if" in § 807.28(a) and (b). We also want to be clear that, though changes to listing information must be reported to FDA between October 1 and December 31 of each year, the information that must be

reported includes any changes that occur since the previous annual listing. For example, if a manufacturer begins producing a device in January and ceases (temporarily or permanently) producing such device in June, this would have to be reported to FDA between October 1 and December 31 of that year.

When an establishment successfully completes a process (e.g., registers and lists for the first time, completes annual registration, creates a new listing, etc.) in FURLS, a confirmation screen appears indicating successful completion of the process. In some cases, the establishment may also receive an email in addition to the confirmation screen. These instances include when an establishment registers and lists for the first time and when FDA sends an email to confirm that they have completed their annual registration. If an establishment does not successfully make it through the process it is trying to complete (e.g., registering and/or listing devices, updating information in the software, etc.), it would not be provided with an email or confirmation screen and would know it was not successfully processed or that an error occurred.

(Comment 12) One comment urged FDA to make available a test or training version of FURLS online that provides access to simulated data or an instruction manual that includes screen shots of the steps in the registration and listing process.

(Response) FDA agrees. Already available, the FURLS Device Registration and Listing Module (DRLM) has online instructions that include screen shots that may be viewed by clicking on the help icon located near the top right of the screen. FDA's DRLM Web site:

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>) provides instruction on who must register and list, who must pay the annual registration user fee and how to register, list, and pay the fee. Assistance is available by sending an email to reglist@cdRH.fda.gov or by calling 301-796-7400.

IV. Legal Authority

We have the legal authority to amend our regulations on foreign and domestic establishment registration and listing for human devices. The statutory basis for our authority includes sections 201, 301, 501, 502, 510, 512, 513, 515, 519-520, 701, 704, 801, and 903 of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i-360j, 371, 374, 381, and 393); and sections 361 and 368 of the Public Health Service Act (42 U.S.C. 264 and 271) (the PHS Act).

Section 510(c) of the FD&C Act requires every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a device to immediately register with the Secretary his name, place of business, and the establishment. The provisions in section 510(b) and (d) of the FD&C Act require annual registration and registration of additional establishments, respectively. As amended by section 222 of FDAAA, section 510(b) of the FD&C Act requires that annual registration take place during the period beginning on October 1 and ending on December 31 of each year. Section 510(i) of the FD&C Act, as amended by section 222 of FDAAA, requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States, upon first engaging in such activity, to immediately register with the Secretary through electronic means, and thereafter to register annually during the period beginning on October 1 and ending on December 31 of each year. These provisions, together with section 701(a) (among others) of the FD&C Act (21 U.S.C. 371(a)), authorize us to require the submission of the registration information specified in the final rule. The information specified in this final rule will help us identify who is manufacturing, preparing, propagating, compounding, processing, repacking, or relabeling devices and where those operations are being

performed. In addition, some information (e.g., official correspondent information) would help us communicate with establishments more effectively and schedule inspections more efficiently.

Section 510(j)(1) of the FD&C Act requires every person who registers to file with the Secretary of the Department of Health and Human Services (the Secretary), at the time of registration, a list of all devices that are being manufactured, prepared, propagated, compounded, or processed by the registrant for commercial distribution. That list must be prepared in the form and manner prescribed by the Secretary and must be accompanied by a copy of labeling (or the label and package insert) and, in some cases, advertising. Section 510(j)(2) of the FD&C Act, as amended by section 223 of FDAAA, requires each person who registers with the Secretary under this section to report listing information updates once each year during the period beginning on October 1 and ending on December 31 of each year. Listing information gives us a current inventory of marketed devices. These provisions and others of the FD&C Act, together with section 701(a) of the FD&C Act, provide authority for requiring the submission of the listing information set forth in this final rule. The device listing information specified in this final rule will help us: (1) Develop a more current, robust inventory of devices as a counter-terrorism measure; (2) administer our postmarket surveillance programs more effectively; (3) facilitate recalls of products; (4) identify devices in short supply in the event of a national emergency; and (5) identify devices marketed in violation of the FD&C Act.

Section 510(p) of the FD&C Act, as amended by section 224 of FDAAA, requires that registration and listing information be submitted electronically, subject to FDA's grant of waivers to individual requestors who meet the criteria set forth in section 510(p). Electronic receipt of registration and listing information will enable us to shift resources from performing more ministerial tasks, such as data entry, to pursuing important public health objectives such as those

described in section I of this document. Electronic receipt of registration and listing information also will help us with the efficient enforcement of the FD&C Act because we would be able to distinguish situations where there has been noncompliance with registration and listing requirements from situations where there have been no changes in information. The failure to register or list is a prohibited act under section 301(p) of the FD&C Act (21 U.S.C. 331(p)) and the failure to do either generally renders a device misbranded under section 502(o) of the FD&C Act (21 U.S.C. 360(o)).

V. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the cost of this final rule is expected to be very small, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure

by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

We received no comments on the analysis of impacts in the March 2010 proposed rule. We have updated but have not made substantial changes to the analysis for this final rule. We used the same baseline as we did in the proposed rule; costs and benefits are estimated relative to the system of paper forms that existed prior to FDA's Internet-based electronic listing and registration system. The new system became operational on October 1, 2007.

We contracted with the Eastern Research Group, Inc. (ERG), to collect data, interview industry experts, and estimate the costs and benefits of the rule. The analysis in support of the effects of the final rule (ERG Memo) is on file with the Division of Dockets Management. ERG identified several very small impacts, both costs and benefits, most of which are too small to generate meaningful numeric estimates.¹ The ERG Memo identified recurring costs associated with this final rule, plus additional costs that would not apply to U.S. establishments. After updating ERG's findings with more recent cost information, we find annual costs of \$340,000 associated with this final rule, and an additional \$138,000 that would only affect non-U.S. establishments. We were unable to quantify specific benefits attributable to the final rule, but the ultimate use of electronic registration and listing data, the mandate under the Bioterrorism Act to collect additional pieces of registration data, and the requirement under the Bioterrorism Act and FDAAA that information be submitted to FDA electronically justify taking this action.

¹ ERG memorandum from Cal Franz, et al., September 15, 2008 (hereinafter referred to as ERG Memo), p. 1.

A. The Need for Regulation

As discussed elsewhere in this preamble, section 224 of FDAAA amended section 510(p) of the FD&C Act to require establishment registrations and device listings to be submitted to FDA by electronic means unless the Secretary grants a waiver from electronic submission requirements. We currently maintain databases that contain establishment registration and device listing information obtained from owners and operators of device establishments. Prior to FDAAA, these databases relied on paper forms submitted by the owners and operators to us, which were then forwarded by us to a data entry contractor for input into our device registration and listing databases.

Our device registration and listing databases play an important role in our efforts to accomplish many regulatory and statutory objectives. For example, we can use this information to identify device manufacturers to facilitate recalls or information alerts in the case of potential safety concerns. We also use it to plan and conduct inspections, administer postmarket surveillance, generate estimates of the number of businesses that are affected by our rulemaking, and to otherwise exercise competent oversight of the device industry.

The quality and completeness of these databases depends on prompt submission of information and the immediate inclusion of the data in our system. Under a paper-based registration and listing system, we were unable to readily verify the accuracy of the information submitted and, in some instances, manufacturers were not timely in informing us of changes. In addition, because we were using physical paper forms, it was possible for information to be mishandled or lost before being added to the system, thereby further reducing the reliability of the databases.

In accordance with FDAAA, the Agency began collecting device establishment registration and device listing information using FURLS, FDA's new Internet-based electronic device establishment registration and device listing system which became operational on October 1, 2007. The electronic submission of information makes the registration and listing process more efficient for industry and allows us to review and use such information more quickly, thus helping to ensure that medical devices will be safe and effective.

Despite the obvious public health advantages to society of using an electronic device registration and listing system, the private returns alone would not be adequate to move the entire device industry to a new registration and listing format that would meet the requirements of section 510(i) and (p) of the FD&C Act. Because the social benefits are largely external to the firms, the large number of entities operating individually cannot be expected to voluntarily move to a new uniform standard. Few entities would choose to adopt a new format without significant private benefits.

B. Background

Revisions to the existing device registration and listing regulations would affect owner-operators of all registered device establishments. Based on a review of our internal databases on September 12, 2011, there are approximately 21,254 owner-operators of approximately 24,000 registered device establishments, and 121,300 listed devices. Of the 24,000 registered establishments, approximately 14,000 are registered as domestic and 10,000 are registered as foreign.

Under the existing regulations, with certain exceptions, owners or operators of establishments that engage in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must, in addition to other

requirements, register their establishments and submit listing information for each of their devices in commercial distribution. Foreign device establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States must comply with the registration and listing requirements, including the requirement to identify a U.S. agent. Until the recent change to electronic submissions mandated by section 224 of FDAAA, all domestic and foreign registration and listing information was submitted using paper forms.

C. The Final Regulation

A major objective of this final rule is to update FDA's regulations at part 807 to reflect the requirement for electronic submission of establishment registration and device listing information as required by FDAAA. A paper-based system of registering and listing is costly. It does not facilitate timely updates, which does not allow for the best use of these data in inspections and recalls. Electronic submission of registration and listing information improves the quality and timeliness of information available to FDA. In addition, a system of electronic registration and listing improves the quality and timeliness of information available to health care professionals and consumers. Furthermore, to the extent that these quality improvements to the registration and listing process facilitate device recalls, complement postmarketing surveillance programs, help ensure the safety of imported devices, improve the scheduling and planning of inspections, and otherwise assist the Agency in carrying out its statutory and regulatory objectives, there is a broad public health benefit. Moreover, the development and maintenance of high quality databases of information about devices and device establishments would enhance future uses of technology in the delivery of health care. An electronic database that contains current and accurate information about devices could, for example, facilitate the

development of technology that would allow for communication among devices, giving them additional functionality and the potential for interoperability.

This final regulation will also slightly modify the types of information that would need to be submitted as registration and listing information. However, these modifications would be minor and are generally consistent with achieving a more accurate and useful database of device industry information.

D. Estimated Impacts

The ERG Memo identifies eight areas where revisions to the current device registration and listing provisions may affect the cost of compliance.² These impacts would stem from provisions associated with:

- The creation of an account on FURLS;
- The requirement for submission of additional information as part of the annual registration process;
- Modifications to requirements relating to registration information updates;
- The requirement for submission of additional information when listing a device;
- Changes relating to the requirement for review and update of device listing information;
- The waiver from the requirement to register and list by electronic means;
- The elimination of the exemptions from registration and listing requirements for foreign establishments whose devices enter a foreign trade zone and are re-exported from the foreign trade zone without having entered U.S. commerce and the exemption for devices that are imported under section 801(d)(3) of the FD&C Act (import-for-export provision); and

² ERG memo, p. 3.

- The elimination of the exemption from registration and listing requirements for contract manufacturers and contract sterilizers who do not commercially distribute the devices.

Because most of the identified regulatory impacts only slightly increase or decrease the costs of registering and listing, sometimes involving offsetting impacts, we present the impacts grouped by the eight impact areas identified previously, as opposed to trying to present the impacts as distinct groups of costs and benefits.

1. Creation of FURLS Accounts

Under the final rule, establishments go through the one-time process of creating a FURLS account. According to ERG, the costs associated with setting up the FURLS account are negligible.³

2. Changes to Annual Registration Information

This final rule could affect the cost to establishments by changing the information they submit in the annual registration process. ERG found that differences in the information collected currently and the requirements under the final rule would be minor and should not increase the time spent completing the registration.⁴ Some of the additional information in the final rule, such as e-mail addresses for the establishment's official correspondent and owner-operator and the universal resource locator (URL) for the establishment's Web site, are currently collected by FDA and there will be little if any additional cost for those establishments not currently providing this information. There will be modest savings associated with the annual registration process, as establishments will be able to access and edit registration information online and will no longer have to wait for physical forms to be mailed from FDA, review them, make edits, and mail the forms back to FDA.

³ ERG memo, p. 4.

⁴ ERG memo, p. 4.

As amended by section 321 of the Bioterrorism Act, section 510(i) of the FD&C Act requires foreign establishments whose devices are imported or offered for import to the United States to identify and provide contact information for importers of the establishment's device that are known to the establishment and also those persons who import or offer for import the device into the United States. According to the ERG memo, foreign establishments identifying importers known to them and persons who import or offer for import the establishments' devices would typically be identifying one or two entities of each type with readily available contact information, so the impact would be negligible.⁵ OMB Circular A-4 directs us to carefully evaluate new U.S. rules that might act as non-tariff barriers to imported goods. As the cost to these foreign establishments will be quite small and will not have a significant adverse effect on trade, the impact on U.S. consumers from this provision will be negligible.

3. Changes Relating to the Requirement to Update Registration Information

Under § 807.22(b)(2), establishments would be required to update their registration within 30 days if their registration information were to change. Current § 807.26 requires that establishments update registration information for a change in ownership or a change in the location of the establishment. As the final rule includes a broader set of circumstances requiring a mandatory update, it has the potential to be slightly more costly. Under the final rule, however, establishments will provide updates electronically, as opposed to submitting such information to FDA using a paper form as required by current § 807.26. ERG found that the ability to submit updated information through FURLS rather than completing and mailing paper forms to result in a net reduction in administrative burden and, therefore, a cost savings to establishments. ERG

⁵ ERG memo, p. 5.

did not quantify the savings, but we estimate it will negate any cost increase from the greater likelihood of a mandatory update.

4. Requirement for Additional Device Listing Information

Under § 807.25, establishments will be required to submit additional information, including 510(k) numbers and HDE numbers among the types of premarket submission numbers submitted to FDA for non-exempt devices. Establishments will also submit all proprietary and brand names under which each device is marketed. Although the Agency already collects proprietary or brand names as part of device listings, the device listing form specified for use under the existing regulation has a single block of 80 characters for proprietary and brand names, which may have been restricting the amount of information establishments have been providing. Establishments using FURLS to list their devices electronically have an unlimited amount of space to provide information and could submit more data. According to the ERG memo, electronic device listings will rarely have more than three proprietary or brand names, so the additional information that establishments will be providing under the final rule is limited.⁶

Under § 807.25(g)(4), establishments will be required to submit 510(k) and HDE numbers for non-exempt devices as part of the listing process. We do not attempt to quantify this very small burden, as owners or operators need only a few minutes to retrieve this information from readily available sources.⁷ Many establishments are already submitting this information electronically and others have been voluntarily submitting this information since FDA began to collect it on a voluntary basis in 2005. The inclusion of the 510(k) number in the device listing will result in significant benefits. Such information would improve our postmarket surveillance efforts by permitting devices to be tracked based on the submission number

⁶ ERG memo, p. 5.

⁷ ERG memo, p. 6.

assigned to the particular device. Absent the 510(k) number, tracking would be done by reported product codes, which do not necessarily correspond to the product codes under which a device was cleared. The process of having the registrant supply the premarket submission number and FDA determine the appropriate product code saves time and saves costs FDA had been incurring addressing incorrectly entered product codes.

5. Changes Relating to Review and Update of Device Listings

Section 510(j)(2) of the FD&C Act, as amended by section 223 of FDAAA, now requires device listings to be updated once each year during the period beginning on October 1 and ending on December 31. Previously, as reflected in the current registration and listing regulations, registrants had to review and update their device listings on a semiannual basis, during June and December. FDA had not strictly enforced this requirement but did encourage establishments to update their listings throughout the year whenever information had changed. The required updates under this final rule are less frequent. Despite this, there is a potential increase in cost from increased enforcement. Any additional impact will be too small to reliably quantify.

6. Requests for a Waiver from Submitting Information Electronically

Under the final rule, parties for whom registering and listing by electronic means is not reasonable may request a waiver from FDA. Because one would only need to have access to a computer, Internet access, and an email address to register and list by electronic means, we do not anticipate many requests for waivers.

For the first few months of operation (i.e., October through December 2007) of the Web-based system, FDA received fewer than 10 requests for waivers from the requirement to submit registration and listing information electronically. As FDA received electronic submissions for

more than 16,000 establishments over that period, these requests amount to about 0.06 percent of the total number of establishments that responded.

Based on information taken from our databases as of September 2011, FDA estimated there were 21,254 owners or operators who collectively registered a total of 24,000 device establishments. If 0.06 percent of the 24,000 total device establishments would request waivers from FDA, there would be 14 requests ($24,000 \times 0.0006$). We estimate submitting a waiver requires an hour of time from a mid-level manager to draft, approve, and mail a letter. At a benefit-adjusted hourly wage of \$41 for a regulatory affairs official, 14 waivers cost \$583.⁸

Additional firms will enter the device industry over the next several years and would need to list and register. Some may request waivers, resulting in small additional costs in the future.

7. Elimination of Exemptions for Some Foreign Establishments

Under current § 807.40(a), foreign establishments are not required to comply with the registration and listing requirements if their device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U.S. commerce. This final rule revises this section to eliminate the exemption.

Current § 807.40(c) exempts devices imported under section 801(d)(3) of the FD&C Act ("import-for-export" provision) from registration and listing requirements. This final rule eliminates this exemption; devices currently exempted will have to be listed and the foreign

⁸ 2010 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor Statistics, last modified May 17, 2011 (www.bls.gov/oes/current/naics4_339100.htm); mean compliance officer wage rate of \$31.68 for medical equipment and supplies manufacturing industry (NAICS 339100) plus a 30-percent increase for benefits.

establishments that manufacture these devices will have to register with FDA. Listing a device requires approximately 2.5 hours,⁹ At \$41 per hour, the cost of listing a device is \$103.

We do not possess a precise estimate of the number of devices affected by the loss of these exemptions. According to the databases maintained by FDA's Division of Import Operations and Policy, 1,344 shipments of devices entered the United States under the "import-for-export" provision in 2006, about 0.13 percent of device shipments.¹⁰ Using 1,344 as a rough estimate of the devices affected by the loss of the "import for export" exemption, the cost to foreign exporters is about \$138,000 (1,344 shipments x 2.5 hours per shipment x \$41/hour). These are one-time costs, as subsequent shipments of the same device would not require an additional registration and listing. The continuing introduction of new devices from foreign exporters will result in some additional costs each year. These additional annual costs, which we do not quantify, will be a small fraction of the one-time \$138,000 cost to foreign exporters.

We do not have a reliable estimate for the number of devices and firms affected by the loss of the exemption for devices imported into foreign trade zones. We expect the number of affected devices and firms to be small. We believe the overall impact on individual foreign firms from the loss of this exemption will be very small.

The elimination of these exemptions will not be costly for domestic device establishments. As these devices are not intended for U.S. commerce, there will be no impact on the domestic market for these devices. The cost per affected device will be small, so the elimination of these exemptions will have a negligible impact on U.S. industries doing "import-for-export" and operating in foreign trade zones. There would potentially be a cost to U.S.

⁹ ERG source on listing time.

¹⁰ ERG memo, p. 10.

industry if an affected foreign establishment was actually a foreign presence of a domestic entity, but we have no knowledge of such establishments.

8. Elimination of Registration and Listing Exemptions for Contract Manufacturers and Sterilizers Who Do Not Commercially Distribute the Devices

Under current § 807.20(a)(2), (c)(1), and (c)(2), contract manufacturers and contract sterilizers are exempt from registration and listing obligations if they make or sterilize a device according to another person's specifications for commercial distribution by the person who developed the specifications. This final rule will eliminate the exemption from registration and listing for contract manufacturers and contract sterilizers who do not commercially distribute. Contract manufacturers and contract sterilizers not currently registering will be required to do so. Registration and listing is a recurring obligation, so there are annual costs associated with this impact.

As of October 2007, there were 1,304 registered contract manufacturers in our registration and listing database who had not previously listed any products. Of these 1,304 establishments, 736 re-registered in 2006. A small number of additional contract manufacturers may not be in our database, but will be registering for the first time because of the loss of an exemption. We use the 736 establishments as our estimate for the contract manufacturers that will need to register and initially list products.

The registration and listing database in September 2011 contained about 121,300 listed devices and 24,000 registered establishments, or about 5.05 devices per establishment. If the estimated 736 affected contract manufacturers have an average of 5.05 devices, there will be 3,717 additional device listings.

Between 1999 and 2006, there was an average of 306 initial contract manufacturer registrations each year. Assuming 306 contract manufacturers initially register each year and there are 5.05 devices per establishment, there will be 1,545 additional listings each year. In the first year of our analysis, we assume 736 existing contract manufacturers and 306 contract manufacturers initially registering for a total of 1,042. At 5.05 devices per establishment, there would be 1,566 additional listings for a total of 5,262 the first year.¹¹

There are 116 registered establishments that perform contract sterilizations only and have no listed devices. Our databases also include 114 contract sterilizers associated with 533 device listings, an average of 4.68 listings per establishment. We assume that the 116 contract sterilizers with no listed devices are establishments currently not required to list but will be required to list under the final rule. Assuming these establishments also have an average of 4.68 listings, there will be 543 additional listings from the loss of the exemption for contract sterilizers.

We assume registration and listing requires 2.5 hours of time per listed device each year.¹² At a labor rate of \$41 per hour, including benefits, registration and listing costs \$103 per device or \$520 per contract manufacturing establishment (\$103 per listing x 5.05 listings). and \$482 per contract sterilizing establishment (\$103 per listing x 4.68 listings). Across all affected contract manufacturers the cost will be a recurring \$539,000 (\$41 per hour x 2.5 hours x 5,262 listings). For contract sterilizers, the cost will be \$56,000 (\$41 per hour x 2.5 hours x 543 listings). Thus, the impact on contract manufacturers and contract sterilizers will be an annual

¹¹ We do not follow the assumption in the ERG memo that half of these contract manufacturers would not register and pay user fees.

¹² ERG memo, p. 9.

\$595,000 (\$539,000 + \$56,000). We may not be aware of some contract sterilizers that have never registered, but there are likely few such firms and do not account for them in our analysis.

The loss of the exemption for contract manufacturers and sterilizers who do not commercially distribute the devices will not only result in social economic costs, but will also result in transfers associated with the payment of user fees. Contract manufacturers and sterilizers that are required to register will be required to pay user fees. According to section 212 of FDAAA, the FY 2012 establishment registration fee is \$2,029. At that rate, we estimate FY 2012 fees of \$2.35 million, \$2.11 million paid by the 1,042 contract manufacturers and \$235,000 paid by the 116 contract sterilizers.

Table 1 of this document summarizes the projected quantified impacts of this final rule. The total annual costs are \$340,000. Foreign establishments will face an additional annual burden of \$138,000 due to the loss of the exemptions from registration and listing requirements relating to devices entering a foreign trade zone that are later re-exported without having entered U.S. commerce and devices that are imported into the United States under section 801(d)(3) of the FD&C Act. There would also be a transfer of \$2.14 million in additional user fees paid by contract manufacturers and sterilizers.

Table 1.--Projected Impacts of the Final Rule

Establishment Category	No. of Affected Establishments/ Devices	Incremental Time	Cost per Hour ¹	Total Annual Cost ³
Requests for a Waiver from Submitting Information Electronically	14 establishments	1 hr	\$41	\$583
Foreign establishments shipping to United States under import-for-export and to foreign trade zones	none ²	2.5 hrs	\$41	\$0 ²
Elimination of Exemptions for Contract Manufacturers	5,262 devices, 1,042 establishments	2.5 hrs	\$41	\$539,000
Elimination of Exemptions for Contract Sterilizers	543 devices, 116 establishments	2.5 hrs	\$41	\$56,000
All other	negligible	--	--	negligible ³
Total	1,172 establishments, 5,805 devices	--	--	\$598,000

¹ Average hourly wage for medical equipment and supplies compliance officer, adjusted for benefits.

² Provision would not be expected to affect U.S. establishments. An estimated 1,344 foreign establishments would face additional annual costs of \$138,000.

³ Estimated incremental time costs are offset by incremental time savings.

Table 2.--Economic Transfers Associated with the Final Rule

From	To	Description	Cost per Entity	Total Cost
1,042 Contract Manufacturers and 116 Contract Sterilizers	U.S. Government	Establishment Registration Fees	\$2,029	\$2.35 million

The final rule will result in benefits associated with an electronic registration and listing database that would provide more up-to-date and complete information. The electronic registration and listing database system could also support future medical and health information technology initiatives. The final rule will increase the efficiency of the registration and listing process by eliminating all or nearly all paper submissions. With registration and listing in an electronic format, we are able to review the submitted information more quickly and can contact

submitting firms immediately through email if any additional information is needed. In addition, a more accurate and more complete database of registered establishments and listed devices benefits patient safety by facilitating timely notification of recalls of certain unsafe devices and prompt identification of the affected manufacturers.

Although the scope of the final rule does not extend beyond registration and listing, the resulting high-quality, electronic database will facilitate future uses of technology for the public benefit. A current electronic database of device information could, for example, facilitate the development of future devices utilizing wireless connectivity and the interoperation of such devices with hospital information systems, or with handheld personal digital assistant (PDA)-type clients used by health care providers or those managing hospital inventories.

Additionally, having a paper-based registration and listing system is inconsistent with section 510(p) of the FD&C Act, as amended by section 224 of FDAAA, and might deter the medical device industry and healthcare providers from investing in new initiatives that would make use of electronic device listing and establishment registration data.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The impact of this final rule is almost entirely attributable to the requirement that contract manufacturers and contract sterilizers register and list. We have estimated the impacts on small entities and find that the costs associated with registering and listing will not be a significant burden for even the smallest of contract manufacturers and contract sterilizers. Moreover, failing to remove this exemption for contract manufacturers and sterilizers would reduce the benefits of this final rule. These benefits include improving the quality and timeliness of information, facilitating device recalls,

complementing postmarket surveillance programs, ensuring the safety of imported devices, and improving the scheduling and planning of inspections. Requiring contract manufacturers and sterilizers to register and list allows for the appropriate oversight of these types of facilities. For other elements of this final rule, the costs per entity are very small and we do not believe that this final rule will have a significant economic impact on a substantial number of small entities.

As described earlier in this preamble, this final rule will revise the Agency's regulations at part 807 to make them consistent with the requirement under FDAAA that the Agency shift to an electronic registration and listing format. The incremental costs to establishments making this switch to electronic registration and listing are so small as to be difficult to quantify. Certain elements of the final rule may be costly to some entities, but the actual incremental costs are estimated to be extremely small. We estimate the cost of submitting a waiver claiming electronic listing and registration to be \$41. The cost of registering and listing a device because of the loss of the exemptions from registration and listing requirements for devices imported into foreign trade zones or imported under section 801(d)(3) of the FD&C Act is not expected to have an effect on domestic establishments. Other elements of the final rule involve the submission of information not currently required but readily available and the estimated cost of compliance will be so small as to be difficult to estimate.

Contract manufacturers and contract sterilizers who do not commercially distribute the devices they make or sterilize will be faced with a new requirement to register and list. We do not know how many of the affected contract manufacturers and contract sterilizers would be categorized as small. As shown in table 1 of this document, we estimate 1,042 affected contract manufacturers and 116 affected contract sterilizers. Our internal databases include some contract manufacturers and sterilizers that have in the past voluntarily registered. A review of the

contract sterilizers in this database indicate many are described in external databases as being part of NAICS code 339113 (Surgical Appliance and Supplies Manufacturing). Because of the specific expertise, capital requirements, and economies of scale associated with contract sterilization, we expect contract sterilizers will have more employees and more revenues per employee than would a typical establishment in this class. Medical device contract manufacturers fit in NAICS code 339112 (Surgical and Medical Instrument Manufacturing). For both of these industry classifications, the U.S. Small Business Administration has defined a small business as one with 500 or fewer employees.¹³

According to the U.S. Census there are 1,340 establishments in class 339112 with 1,293 of them (96 percent) having fewer than 500 employees.¹⁴ Census information on class 339113 lists 2,219 establishments, with 2,189 of them (99 percent) having fewer than 500 employees.¹⁵ Applying these profiles to our estimated contract manufacturers and contract sterilizers, there would be 1,000 small affected contract manufacturers (96 percent of 1,042) and 116 small affected contract sterilizers (99 percent of 118).

For class 339112, we consider the establishment group of establishments with 10 to 19 employees, the smallest group for which data are provided. According to Census data, there are 183 establishments with a total value of shipments of \$468 million. The average value of

¹³ U. S. Small Business Administration, “Table of Small Business Size Standards Matched to North American Industry Classification System Codes,” March 26, 2012. http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

¹⁴ U.S. Census Bureau, 2007 Economic Census, “Surgical and Medical Instrument Manufacturing,” released November 16, 2010, http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-ib_type=NAICS2007&-NAICS2007=339112.

¹⁵ U.S. Census Bureau, 2007 Economic Census, “Surgical Appliance and Supplies Manufacturing,” released November 16, 2010, http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731SG3&-ib_type=NAICS2007&-NAICS2007=339113.

shipments is \$2.6 million. As discussed in section V.D of this document, establishment registration user fees are \$2,029 for FY 2012, and as shown in table 1 of this document, the estimated annual burden of listing a device is 2.5 hours at \$41 per hour, or \$103. A small contract manufacturer with a single listed device would face an annual burden of \$2,029 plus \$103, or \$2,132, which is 0.08 percent of annual revenues.

Table 3.--Small Entity Characteristics and the Impact of the Final Rule

	Surgical and Medical Instrument Manufacturing (NAICS 339112)	
Number of Employees	10 to 19	20 to 49
Total Value of Shipments (\$1000)	468,343	1,293,992
Number of Establishments	183	183
Average Value of Shipments (\$)	2,559,000	7,071,000
Annual Costs as a Percentage of the Average Value of Shipments	0.08%	0.03%

For class 339113, considering establishments with 10 to 19 employees, the smallest group for which data are provided, there are 302 establishments a total value of shipments of approximately \$798 million. The average value of shipments is \$2.6 million. Contract sterilizers will face an annual establishment fee of \$2,029 plus a cost of \$103 per listed device. A small contract sterilizer with 2 listed devices will face an annual burden of \$2,029 plus \$206, \$2,235. This amount is equal to 0.17 percent of annual revenues, well below typical thresholds cited for significant impacts.

Table 4.--Small Entity Characteristics and the Impact of the Final Rule

	Surgical Appliance and Supplies Manufacturing (NAICS 339113)	
Number of Employees	10 to 19	20 to 49
Total Value of Shipments (\$1000)	797,774	1,686,427
Number of Establishments	302	324
Average Value of Shipments (\$)	2,642,000	5,205,000
Annual Costs as a Percentage of the Average Value of Shipments	0.08%	0.04%

A \$41 burden associated with a waiver request is be about 0.01 percent of revenues for a small entity with revenues in the hundreds of thousands of dollars. As discussed earlier in section V.D of this document, other impacts associated with this final rule are all extremely small. We therefore conclude that the final rule will not have a significant impact on a substantial number of small entities. Affected entities currently possess the skills required to comply with the provisions of this final rule.

FDA considered regulatory alternatives such as not regulating and not requiring registration and listing by contract manufacturers and contract sterilizers who do not commercially distribute devices. As explained earlier in this preamble, the electronic submission of information is mandated under FDAAA. The benefits associated with Agency oversight of contract manufacturers and contract sterilizers justify the estimated costs of requiring that they register and list.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual

reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Implementation Electronic Submission of Medical Device Registration and Listing (OMB Control No. 0910-0625)--Revision

Description: In accordance with the collection of information entitled "Electronic Submission of Medical Device Registration and Listing," medical device establishment owners and operators will be required to electronically submit establishment registration and device listing information.

Section 510(c) of the FD&C Act requires owners or operators of domestic establishments upon first engaging in the "manufacture, preparation, propagation, compounding, or processing" of a device or devices in those establishments to immediately register their name and place of business and such establishment. Section 510(a)(1) of the FD&C Act defines the term "manufacture, preparation, propagation, compounding, or processing" to include "repackaging or otherwise changing the container, wrapper, or labeling of any * * * device package in furtherance of the distribution of the * * * device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user."

Section 510(a)(2) of the FD&C Act mandates that the term "name" include, among other things, the name of each partner of a partnership, and the name of each corporate officer and director of a corporation. An owner or operator of a registered establishment must also immediately register any additional establishment that he owns or operates in any State and in which he begins the "manufacture, preparation, propagation, compounding, or processing" of a device (section 510(d) of the FD&C Act). An owner or operator of any establishment that

engages in these activities must also re-register its establishment once each year during the period beginning on October 1 and ending on December 31 of each year (section 510(b) of the FD&C Act, as amended by FDAAA).

Section 510(i) of the FD&C Act contains certain registration requirements pertaining to foreign establishments (e.g., submission of the name of each importer of the establishment's device in the United States that is known to the establishment, submission of the name of each person who imports or offers for import the establishment's device to the United States for purposes of importation). Section 510(g) of the FD&C Act provides for certain exemptions from the registration requirements. In addition, section 510(p) of the FD&C Act, as amended by FDAAA, requires the electronic submission of device registration and listing information unless the Secretary grants a request for a waiver because use of electronic means is not reasonable for the person requesting the waiver.

Section 510(j)(1) of the FD&C Act requires that every person who registers must, at the time of registration, submit a list of all devices that are being manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution which have not been previously listed by him or her. This information must be submitted in the form and manner prescribed by the Secretary (section 510(j)(1) of the FD&C Act). Prior to FDAAA, section 510(j)(2) of the FD&C Act required certain changes in listing information to be reported every June and December, including any material changes in information previously submitted under the listing provisions. This information must now be provided only once each year during the period beginning on October 1 and ending on December 31.

Section 510(e) of the FD&C Act permits the Secretary to prescribe a uniform system for the identification of devices intended for human use and may require that persons who are

required to list such devices under section 510(j) shall list such devices in accordance with such a system. The disclosure provision in section 510(f) of the FD&C Act requires the Secretary to make available for inspection any registration filed under section 510. Section 510(f) also provides that certain listing information must be exempt from disclosure unless the Secretary finds that such exemption would be inconsistent with protection of the public health.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: Identification of establishments producing marketed medical devices, identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, facilitation of recalls for devices marketed by owners and operators of device establishments, identification and cataloguing of marketed devices, administering postmarketing surveillance programs for devices; identification of devices marketed in violation of the law; identification and control of devices imported into the country from foreign establishments; and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act.

The electronic collection of establishment registration and device listing information from medical device establishment owners and operators also furthers the purpose of several statutes, including: The FDAAA, the Bioterrorism Act, MDUFMA, and GPEA.

Description of Respondents: Owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements.

The total annual estimated burden imposed by this collection of information is 99,470 hours annually.

FDA estimates the burden of this collection of information as follows:

Table 5.--Estimated Annual Reporting Burden¹

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.20(a)(5) ² Submittal of Manufacturer Information by Initial Importers	3673	8,594	1	8,594	1.75	15,040
807.20(a)(5) ³ Submittal of Manufacturer Information by Initial Importers	3673	8,594	3	25,782	0.1	2,578
807.21(a) ³ Creation of Electronic System Account	3673	3,559	1	3,559	.5	1,780
807.21(b) ² Annual Request for Waiver From Electronic Registration & Listing		14	1	14	1	14
807.21(b) ³ Initial Request for Waiver From Electronic Registration & Listing		4	1	4	1	4
807.22(a) ³ Initial Registration & Listing	3673	3,539	1	3,539	0.5	1,770
807.22(b)(1) ³ Annual Registration	3673	20,335	1	20,335	0.75	15,266
807.22(b)(2) ³ Other Updates of Registration	3673	4,176	1	4,176	0.5	2,088

807.22(b)(3) ³ Annual Update of Listing Information	3673	19,875	1	19,875	1	19,875
807.26(e) ³ Labeling & Advertisement Submitted at FDA Request		71	1	71	1	71
807.34(a) ² Initial Registration & Listing When Electronic Filing Waiver Granted		14	1	14	1	14
807.34(a) ³ Annual Registration & Listing When Electronic Filing Waiver Granted		4	1	4	1	4
807.40(b)(2) ³ Annual Update of U.S. Agent Information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) ³ U.S. Agent Responses to FDA Requests for Information	3673	1,535	1	1,535	0.25	384
807.41(a) ³ Identification of Initial Importers by Foreign Establishments	3673	10,329	1	10,329	0.5	5,165
807.41(b) ³ Identification of Other Parties That Facilitate Import by Foreign Establishments	3673	10,329	1	10,329	0.5	5,165
Total One Time Burden						15,068
Total Recurring Burden						54,958

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²One Time Burden.

³Recurring Burden.

Table 6.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
807.25(d) ² List of Officers, Directors & Partners	23,806	1	23,806	.25	5,952
807.26 ² Labeling & Advertisements Available for Review	11,746	4	46,984	.5	23,492
Total					29,444

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²Recurring burden.

The reporting and recordkeeping estimated burden for electronic registration and listing under OMB number 0910-0625 for the proposed rule is larger for reporting and smaller for recordkeeping than the burden estimated for the final rule (7,911 and 11,977 smaller, respectively) because of more accurate re-estimates using information from our FURLS database.

The currently approved reporting and recordkeeping burden for electronic registration and listing under OMB number 0910-0625 is 71,319. The estimated reporting and recordkeeping burden for electronic registration and listing under the rule is 99,470 hours, an increase of 28,151 hours. This increase is due to the incremental increase of respondents no longer exempt from these requirements weighed against the change in reporting requirements for all owner operators and the decrease in the overall number of device establishments that have registered since OMB approved the collection of information under control number 0910-0625.

Burden estimates are based on recent experience with the existing medical device registration and listing program and the economic analysis provided by ERG. The changes to the actual data collected are very minor, with one exception. We are assuming that it will take approximately the same amount of time to enter the data online using FURLS as it does to use the portable document format (PDF)-enabled forms that had been used for initial establishment registration prior to FURLS becoming operational in October 2007. Any additional burden associated with creating and using the Web-based system accounts (as shown in table 3 of this document under § 807.21(a)) should be offset by the elimination of the need to re-enter identifying information concerning the establishment or product every time registration or listing information is updated, which was the case when updating such information using the PDF-enabled forms.

The recurring burden for the new data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on the ERG memo. This report stated that foreign establishments would typically be identifying one or two importers and one or two persons who import or offer for import with readily available contact information.

The estimates for creation of new user accounts under § 807.21(a) are based on the current number of owners or operators, and experience in account creation using the existing FURLS for Food Facility Registration. The estimates for the recurring years assume a similar increase in the number of new owner or operator numbers as were created in FY 2006.

The estimate for § 807.25(d) in table 5 of this document (recordkeeping burden) reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested

by FDA. However, it is assumed that some effort will need to be expended to keep such lists current.

The requirements shown in table 5 for § 807.26 (renumbered from § 807.31), have not changed based on this revision to the registration and listing regulations. They reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records when requested by FDA. They are based on experience FDA has had with the existing regulation.

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 807.35(b) refer to currently approved collections in 21 CFR part 607 OMB control number 0910-0052 and 21 CFR part 207 OMB control number 0910-0045. This rule will not impact the burden in 0910-0052 and 0910-0045 which are already accounted for in those information collections.

Before the effective date of this final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

1. Bureau of Labor Statistics, May 2008, National Industry-Specific Occupational Employment and Wage Estimates, NAICS 339100--Medical Equipment and Supplies Manufacturing, Occupation (SOC code): (131041)

http://www.bls.gov/oes/current/naics4_339100.htm.

2. Eastern Research Group memorandum from Cal Franz, Derek Singer, and John Eyraud to FDA, September 15, 2008.

3. Office of Management and Budget, Circular A-4, Regulatory Analysis, Washington, DC, 2003, http://www.whitehouse.gov/omb/circulars_a004_a-4/Circular A-4 | The White House

List of Subjects in 21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and Recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 807 is amended as follows:

PART 807--ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR
MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

2. Amend § 807.3 by:

- a. Adding "and" at the end of paragraph (e)(3);
- b. Removing ";and" at the end of paragraph (e)(4) and adding a period in its place;
- c. Removing paragraph (e)(5);
- d. Revising paragraph (i);
- e. Redesignating paragraphs (k) through (s) as paragraphs (l) through (t), respectively;

and

- f. Adding a new paragraph (k) and adding paragraphs (u) through (y).

The revisions and additions read as follows:

§ 807.3 Definitions.

* * * * *

(i) Restricted device means a device for which a requirement restricting sale, distribution, or use has been established by a regulation issued under section 520(e) of the act, by order as a condition of premarket approval under section 515(d)(1)(B)(ii) of the act, or by a performance standard issued in accordance with sections 514(a)(2)(B)(v) and 514(b) of the act.

* * * * *

(k) Product code means the code used by FDA to identify the generic category of a device.

* * * * *

(u) Fiscal year means the FDA fiscal year, which runs from October 1 through September 30.

(v) FURLS means the Food and Drug Administration's Unified Registration and Listing System,

(w) FDA premarket submission number means the number assigned by FDA to a premarket device submission, such as a Premarket Approval Application (PMA); Humanitarian Device Exemption (HDE); New Drug Application (NDA); Biologics License Application (BLA); de novo classification petition; or Premarket Notification (510(k)).

(x) Importer means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's device that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient.

(y) Person who imports or offers for import means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

3. Revise § 807.20 to read as follows:

§ 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use, including any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party;

(2) Sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person;

(3) Repackages or relabels a device;

(4) Reprocesses a single use device that has previously been used on a patient;

(5) Acts as an initial importer as defined in § 807.3(g), except that initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importer;

(6) Manufactures components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g. blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(c) Registration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in § 807.3(t), and who does not manufacture, repackage, process, or relabel a device.

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and

tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.26 remain applicable.

(e) Owners and operators of establishments that manufacture devices licensed under section 351 of the Public Health Service Act as well as licensed biological products used in the manufacture of a licensed device must register and list following the procedures set out in part 607 of this chapter, instead of the procedures for registration and listing contained in this part.

§ 807.22 [Removed]

4. Remove § 807.22.

§ 807.21 [Redesignated as § 807.22]

5. Redesignate § 807.21 as § 807.22.

6. Add new § 807.21 to subpart B to read as follows:

§ 807.21 How to register establishments and list devices.

(a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information to us using our electronic device registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section:

- (1) Initial establishment registration information as required by §§ 807.22(a) and 807.25;
- (2) Updates to registration information as required by §§ 807.22(b) and 807.25;
- (3) Initial device listing information as required by §§ 807.22(a), 807.25, and 807.28;

(4) Updates to device listing information as required by §§ 807.22(b), 807.25, and 807.28, including updates to reflect the discontinuance or resumption of the commercial distribution of a previously-listed device as specified at paragraphs (d) and (e) of § 807.28.

(b) If the information under § 807.21(a) cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants must send a letter to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2621, Silver Spring, MD 20993-0002, that includes the following information:

(1) The name and address of the device establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment has already registered in the past, the letter should also include the owner or operator number, registration number, and any listing numbers previously assigned by FDA for devices manufactured at that establishment.

(2) Information about whether the company is an initial importer as defined in § 807.3(g) and, if so, whether it also conducts any other activities or operations relating to devices.

(3) A statement that use of the Internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. The statement must be signed by the owner or operator of the establishment, or by a person employed by the owner or operator who is authorized to make the declaration on behalf of the owner or operator.

(c) Those owners or operators who have obtained a waiver from filing registration and listing information electronically should refer to § 807.34 for information on how to submit such information by postal mail.

(d) When additional device listing information (e.g., copies of labeling or advertisements) is requested by FDA as described at § 807.26(e), such information may be submitted by postal mail or electronically by e-mail, but will not be submitted using the FDA electronic device registration and listing system.

7. Revise newly redesignated § 807.22 to read as follows:

§ 807.22 Times for establishment registration and device listing.

(a) Initial registration and listing. An owner or operator of an establishment who has not previously entered into an operation described in § 807.20(a) shall register within 30 days after entering into such an operation and submit device listing information at that time.

(b) Registration and listing updates. Owners or operators shall review and update all of their establishment registration and device listing information that is on file at FDA, documenting any changes that were not previously reported as follows:

(1) Annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year;

(2) Updates to the registration information as described in § 807.25(b) shall be made within 30 days of any change to such information;

(3) Every fiscal year, during the period beginning on October 1 and ending on December 31, owners or operators shall review and update all of their device listing information that is on file at FDA, reporting any changes or deletions to listings and any new listings that were not previously reported. The accuracy of all information on file must be confirmed each year regardless of whether any changes were made to the owner or operator's list of devices; and

(4) Changes to listing information may also be made at other times, such as when a device is introduced into commercial distribution, when a change is made to a previously-listed device, or when a previously-listed device is removed from commercial distribution.

(c) Failure to submit required information. Failure to submit any of the required information on time, as specified in paragraphs (a) and (b) of this section, will put the establishment in a "failed to register" or "failed to list" status as applicable. The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until such time as the owner or operator submits and FDA processes the required information.

8. Revise § 807.25 to read as follows:

§ 807.25 Information required for device establishment registration and device listing.

(a) All owners or operators that are subject to the registration and listing requirements of this part shall provide such information to us by using the FDA electronic device registration and listing system, unless granted a waiver from electronic submission in accordance with § 807.21(b). Electronic submissions of registration and listing information must comply with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30 of this chapter. Those owners or operators granted a waiver from electronic submission should refer to paragraphs (c) and (g) of this section and § 807.34 for instructions on how to submit device registration and listing information.

(b) Registration information required to be submitted includes: The name and mailing address of the device establishment; the Web site address of the device establishment, if any; the name, address, phone number, fax number, and email address of the owner or operator; the

name, address, phone number, fax number, and email address of the establishment's official correspondent; and all trade names used by the establishment.

(c) Owners or operators who have been granted a waiver from electronic filing must submit the establishment registration information described in paragraph (b) of this section, except for the Web site and email address information, in paper form using the procedures set forth in § 807.34.

(d) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment registered by the owner or operator and to furnish this information to FDA upon request.

(e) For each establishment, an official correspondent must be designated by the owner or operator to serve as a point of contact with FDA on matters relating to the registration of device establishments and the listing of device products. Each owner or operator shall also provide FDA with the name of a contact person at the owner or operator's offices who will be responsible for identifying the official correspondent for each establishment. The owner or operator contact person will be the official correspondent in the event no one else has been properly designated. The official correspondent is responsible for:

(1) Providing FDA with all required registration and listing information electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b) ;

(2) Receiving all correspondence from FDA concerning registration and listing;

(3) Supplying, when requested by FDA, the names of all officers, directors, and partners;

and

(4) Receiving communications from FDA by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(f) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the Federal Food, Drug, and Cosmetic Act.

(g) Device listing information must be submitted to FDA electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b). Owners or operators who have been granted a waiver must submit the required device listing information, including information required by this paragraph, § 807.28, and any listing information requested by FDA under § 807.26(e), in paper form using the procedures set forth in § 807.34. The information required for each device listed includes:

(1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed.

(2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976.

(3) The proprietary or brand name(s) under which each device is marketed.

(4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, granted de novo classification petition, or approved humanitarian device exemption for each device listed that is subject to sections 505, 510(k), 513(f)(2), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, which includes devices that are not exempt from premarket notification and approval.

(5) Each activity or process that is conducted on or done to the device at each establishment, such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only.

§ 807.26 [Removed and Reserved]

9. Remove and reserve § 807.26.

§ 807.31 [Redesignated as § 807.26]

10. Redesignate § 807.31 as § 807.26.

11. Amend newly redesignated § 807.26 by adding paragraph (f) to read as follows:

§ 807.26 Additional listing information.

* * * * *

(f) Labeling, advertisements, and other information to be submitted upon request in accordance with paragraph (e) of this section may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system. Electronic submissions of such information must comply with part 11 of this chapter, except for the requirements in § 11.10 (a), (c) through (h), and (k), and the corresponding requirements in § 11.30 of this chapter. The information provided in electronic format must be in a form that we can process, review, and archive.

§ 807.30 [Redesignated as § 807.28]

12. Redesignate § 807.30 as § 807.28.

13. Revise newly redesignated § 807.28 to read as follows:

§ 807.28 Updating device listing information.

(a) Updating of device listing information is required if an additional establishment begins to engage in any of the activities described in § 807.3(d) with respect to a listed device, such as manufacturing, developing specifications, repackaging, relabeling, or otherwise processing the device. Updating of the listing is also required if an establishment begins performing another activity on or to the device, or ceases to perform an activity on or to the device that had previously been identified on the device listing.

(b) An owner or operator shall create a new device listing using the FDA electronic device registration and listing system:

(1) If introducing into commercial distribution an exempt device identified with a product code that is not currently listed by the owner or operator; or

(2) If introducing into commercial distribution a non-exempt device with an FDA premarket submission number that is not currently listed by the owner or operator.

(c) All device listings for foreign establishments must be submitted before the device may be imported or offered for import into the United States.

(d) An owner or operator who discontinues commercial distribution of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if:

(1) All devices under an exempt product code have been discontinued or

(2) All devices associated with an FDA premarket submission number have been discontinued.

(e) If commercial distribution of a discontinued device is resumed, the owner or operator must reactivate the previously-discontinued listing using the electronic device registration and

listing system. Any changes to the listing information for the product that is the subject of the listing such as a new establishment, new activity, or new proprietary name must be made using the electronic device registration and listing system at the time the listing is reactivated.

(f) FDA will assign one listing number for all devices exempt from premarket notification requirements under a single product code. For products not exempt from premarket notification requirements, a single listing number will be assigned by FDA for each FDA premarket submission number.

14. Add § 807.34 to subpart B to read as follows:

§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25, (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002.

(b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.

(c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a "failed to register" or "failed to list" status as applicable.

The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until the required information is submitted to and processed by FDA.

15. Amend § 807.35 by revising paragraphs (a) and (b) to read as follows:

§ 807.35 Notification of registrant.

(a) The Food and Drug Administration will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

* * * * *

16. Revise § 807.37 to read as follows:

§ 807.37 Public availability of establishment registration and device listing information.

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA Web site, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.

(b) The following listing information will not be available for public inspection or posted on the FDA Web site:

(1) For contract manufacturers, contract sterilizers, and private label manufacturers, the proprietary or brand name(s) under which a device is marketed and the FDA-assigned premarket submission number, if this information would reveal a confidential business relationship;

(2) FDA-assigned listing numbers.

17. Revise the heading of subpart C to read as set forth below:

Subpart C--Procedures for Foreign Device Establishments

18. Amend § 807.40 by revising paragraphs (a) and (c) and by adding paragraph (d) to read as follows:

§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures in this section, § 807.41, and subpart B of this part. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of FDA for matters relating to the registration of device establishments and the listing of device products.

* * * * *

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.

(d) The device establishment registration and device listing information shall be in the English language.

19. Add § 807.41 to subpart C to read as follows:

§ 807.41 Identification of importers and persons who import or offer for import.

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax

numbers, email address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which of the establishment's listed products each importer receives from the foreign establishment.

(b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.

(c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

Dated: July 27, 2012.
Leslie Kux,
Assistant Commissioner for Policy.